

REMARKS

The Final Office Action of has been received and reviewed.

Claims 16, 18, 21-23, 31, 32, 34 and 36-38 are currently pending in the application.

Claims 33 and 35 have been canceled.

Claims 16 and 18 have been amended to recite that the transition metal complex comprises "at least one atom of a transition element and at least one ligand". Support for this amendment can be found on page 10, lines 4-22 of the specification.

Claim 16 has been amended to clarify the water-soluble acidic macromolecular substances of the present invention.

Claim 18 has been amended to be in independent form.

Claim 22 has been amended to depend from claim 18.

New claims 36-38 find support in claims 31, 32 and 34, respectively.

All cancellations and amendments are made without prejudice or disclaimer. No new matter has been added by way of the above-amendment.

Reconsideration is respectfully requested.

Finality of Office Action

The Office Action of April 13, 2005 is indicated to be final. However, Applicants believe that the finality of the outstanding Office Action is improper. Some of the amended claims, for instance, claim 16, could have been previously rejected. Specifically, claim 16 embodies substantially the same subject matter of previous claims 1, 6 and 16. Therefore, Applicants respectfully submit that the finality of the Office Action is improper and that the finality should be withdrawn. Accordingly, entry of this amendment into the Official Record is warranted, and in the event that the Examiner does not find the inventive claims patentable, Applicants respectfully request a complete Office Action (as opposed to a brief summary provided in an Advisory Action).

Claim Interpretation

The Examiner asserts that the phrase “transition metal complex” has not been defined by Applicants and thus any compound comprising a “transition metal” is considered to anticipate this term. (See, Office Action of April 13, 2005, hereinafter referred to as “Office Action,” at page 3). However, the specification provides a detailed discussion of what is intended to be encompassed by a “transition metal complex.” For instance, see page 9, lines 9-13, page 9, line 25-page 10, line 3, and page 10, lines 4-22 of the as-filed Specification.

The Examiner further asserts that the phrases “ α -type polymerase” and “non- α , non-pol I type DNA polymerase” have not been defined by Applicants. However, these terms are discussed in the present Specification at pages 1-3. To further define these terms, the Office is referred to the reference *Journal of Bacteriology*, 165:7803-7811 (1997) and *Gene*, 165:103-107 (1995) (copies of references attached hereto as Appendix A). It is submitted that “non- α , non-polI type DNA polymerase” refers to DNA polymerases without properties of the above-mentioned “ α -type DNA polymerase” or “polI type DNA polymerase.” These terms are sufficiently described in the as-filed Specification at page 11, line 21 to page 13, line 17 to the extent that a person of ordinary skill in the art would fully understand the meaning of these terms.

Rejections Under 35 U.S.C. § 102(b)

Anticipation based on Demeke et al.

Claim 16 stands rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Demeke et al., *Biotechniques*, 12:332, 334 (1992) (hereinafter referred to as “Demeke et al.”). (See, Office Action, at page 4). Applicants respectfully traverse the rejection as set forth herein.

Specifically, the Examiner alleges that Demeke et al. anticipate the limitations of claim 16 because Demeke et al. teach a DNA synthesis reaction composition comprising Taq DNA polymerase and one of the following polysaccharides: carrageenan, pectin and dextran sulfate, together with reaction components necessary for DNA synthesis. (Office Action, at page 4). The amendment to claim 16 removes from the Markush group of the water-soluble macromolecular substances (or water soluble salts thereof) carrageenan, pectin and dextran

sulfate. Therefore, since Demeke et al. do not recite all the elements of amended claim 2, Demeke et al. cannot anticipate amended claim 16.

Reconsideration and withdrawal of the anticipation rejection of claim 16 is respectfully requested.

Anticipation based on Tasa et al.

Claim 16 stands rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Tasa et al., *Meth. Mol. Cel. Bio.*, 5:122-124 (1995) (hereinafter referred to as "Tasa et al."). (See, Office Action, at page 4). Applicants respectfully traverse the rejection as set forth herein.

Specifically, the Examiner alleges that claim 16 is anticipated by Tasa et al. because Tasa et al. teach a DNA synthesis reaction comprising a Taq DNA polymerase and heparin. However, as amended, claim 16 does not recite heparin as an element. Thus, Tasa et al. do not recite all the elements of amended claim 16 and therefore Tasa et al. cannot anticipate claim 16.

Reconsideration and withdrawal of the anticipation rejection of claim 16 is respectfully requested.

Anticipation based on Loeb et al.

Claim 16 stands rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Loeb et al., U.S. Patent No. 4,072,574 (hereinafter referred to as "Loeb et al."). Applicants respectfully traverse the rejection as set forth herein.

Specifically, the Examiner alleges that claim 16 is anticipated by Loeb et al. because Loeb et al. teaches a DNA synthesis reaction comprising an AMV DNA polymerase and a transition metal complex containing silver, cobalt, chromium, copper, iron, manganese or nickel. However, these "metal compounds" listed in Table 1 of Loeb et al. are merely metal salts, not metal complexes, comprising at least one atom of a transition element, and at least one ligand, as recited in amended claim 16. Since Loeb et al. does not recite every element of claim 16, Loeb et al. cannot anticipate claim 16.

Reconsideration and withdrawal of the anticipation rejection of claim 16 is respectfully requested.

Anticipation based on Diring et al.

Claim 16 stands rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Diring et al., U.S. Patent No. 5,153,181 (hereinafter referred to as "Diring et al."). Applicants respectfully traverse the rejection as set forth herein.

Specifically, the Examiner alleges that since Diring et al. teach a DNA synthesis composition comprising SR-D reverse transcriptase and chondroitin sulfate, heparin or dextran sulfate, Diring et al. anticipate claim 16. (See Office Action at page 5). However, as amended, claim 16 does not recite chondroitin sulfate, dextran or heparin. Since Diring et al. do not recite each and every element of claim 16, Diring et al. cannot anticipate claim 16.

Reconsideration and withdrawal of the anticipation rejection of claim 16 is respectfully requested.

Anticipation based on Koster et al.

Claims 22, 23 and 35 stand rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by Koster et al., U.S. Patent No. 5,928,906 (hereinafter referred to as "Koster et al."). Applicants respectfully traverse the rejection as set forth herein.

Specifically, the Examiner alleges that Koster et al. teach a composition comprising two or more DNA polymerases having 3'-5' exonuclease activity that is not reduced and comprising an α -type DNA polymerase and a non α -type DNA polymerase. However, as amended, claim 22 now depends from claim 18. Claim 18 has also been amended to recite many elements not present in Koster et al. For instance, claim 18 is directed to a composition comprising a DNA synthesis reaction-enhancer which is selected from a group consisting of a transition metal complex, wherein the transition metal complex is comprised of at least one atom of a transition element and at least one ligand. Koster et al. do not recite the element of "at least one transition

element and at least one ligand.” Furthermore, Koster et al. do not recite any of the water-soluble acidic macromolecular substances or water-soluble salts thereof, as recited in amended claim 18. Thus, as amended, claim 22 cannot be anticipated by Koster, et al.

Dependent claim 23 is not anticipated as, *inter alia*, depending from a non-anticipated base claim, amended claims 18 and 22.

Reconsideration and withdrawal of the anticipation rejection of claims 22 and 23 are respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Obviousness Rejections Based on Demeke et al. in view of Barnes et al.

Claims 18 and 21 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Demeke et al. in view of Barnes et al. Applicants respectfully traverse the rejections as hereinafter set forth.

M.P.E.P. § 706.02(j) sets forth the standard for an obviousness rejection as follows:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be ***some suggestion or motivation***, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). (Emphasis added).

Specifically, it was asserted that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used two polymerases with different 3’-5’ exonuclease activities of Barnes et al. in the composition of Demeke et al. (See Office Action at page 6). However, neither Demeke et al. nor Barnes et al. teach all the elements of claim 18 as amended. Claim 18, as amended, is directed to a DNA synthesis reaction composition comprising a DNA synthesis reaction-enhancer. Demeke et al. do not teach the use

of the recited reaction enhancers to improve DNA synthesis reactions. To the contrary, Demeke et al. teach that addition of such molecules decreases DNA synthesis or acts as an inhibitor of DNA synthesis. Thus, Demeke et al. teach away from the present invention and **would not provide any motivation** for one of ordinary skill in the art to combine Demeke et al. with any other reference for the purpose of enhancing DNA synthesis. A reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. *Dow Chem. Co. v. American Cyanamid Co.* 816 F2d 617, (CAFC 1987). In determining the scope and content of the prior art, and determining whether the prior art suggested the claimed invention, the references "must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention." *Akzo N.V. v. United States Int'l Trade Comm'n*, 1 USPQ2d 1241, 1246 (Fed. Cir. 1986); *In re Fine*, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). Therefore, Demeke et al. and Barnes et al. cannot render claim 18 *prima facie* obvious under 35 U.S.C. § 103(a).

Dependent claim 21 is non-obvious, *inter alia*, as depending from a/an non-obvious base claim, amended claim 18.

Reconsideration and withdrawal of the obviousness rejection of claims 18 and 21 are requested.

Obviousness Rejections Based on Demeke et al. in view of Barnes et al. and in view of Stratagene Catalog

Claims 31-34 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Demeke et al. in view of Barnes et al. and in view of Stratagene Catalog page 39, 1988. Applicants respectfully traverse the rejections as hereinafter set forth.

Specifically, the Examiner alleges that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the compositions of Demeke et al. and Barnes et al. into a kit format as disclosed in the Stratagene Catalog reference. (See Office Action at page 7).

Additionally, claim 31 depends from claim 16 and as amended, also depends from claim 18. Both claims 16 and 18 have been amended to recite elements not present in either Demeke et

al. or Barnes et al. Therefore, since all elements of the recited claims are not present in the literature cited, these references cannot render claim 31 *prima facie* obvious.

Furthermore, as stated above, Demeke et al. actually teach away from combining the references because Demeke et al. illustrate the inhibitory effect of the DNA synthesis reaction-enhancer recited in amended claim 18. As mentioned above, a reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. *Dow Chem. Co.* at 617.

Dependent claims 32 and 34 are non-obvious, *inter alia*, as depending from non-obvious base claims, amended claims 16 and 18.

Reconsideration and withdrawal of the obviousness rejection of claims 31, 32 and 34 are requested.

Obviousness Rejections Based on Tasa et al. in view of Barnes et al.

Claims 18 and 21 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Tasa et al. in view of Barnes et al. (*Id.*, at page 6). Applicants respectfully traverse the rejections as hereinafter set forth.

Specifically, the Examiner alleges that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used two polymerases with different 3'-5' exonuclease activities of Barnes et al. in the composition of Tasa et al. (see Office Action at page 8). However, neither Barnes et al. nor Tasa et al. teach all the elements of claim 18 as amended. Tasa et al. report that heparin has an inhibitory effect on DNA synthesis reactions. Thus, Tasa et al. do not teach or recite the heparin as an enhancer of DNA synthesis reactions. One of ordinary skill in the art would not be motivated to combine Tasa et al. with Barnes et al. to arrive at a DNA synthesis reaction with an enhancer selected from a group including heparin. As mentioned above, a reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. *Dow Chem. Co.* at 617.

Therefore, Barnes et al. and Tasa et al. cannot render claim 18 *prima facie* obvious under 35 U.S.C. § 103(a).

Dependent claim 21 is non-obvious, *inter alia*, as depending from a/an non-obvious base claim, amended claim 18.

Reconsideration and withdrawal of the obviousness rejection of claims 18 and 21 are requested.

Obviousness Rejections Based on Tasa et al. in view of Barnes et al. and in view of Stratagen Catalog

Claims 31-34 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Tasa et al. in view of Barnes et al. and in view of Stratagene Catalog page 39, 1988 (*Id.*, at page 8). Applicants respectfully traverse the rejections as hereinafter set forth.

Specifically, it was thought that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the compositions of Tasa et al. and Barnes et al. into a kit format as disclosed in the Stratagene Catalog reference. (*Id.*).

Claim 31 depends from claim 16 and as amended. Also, the Examiner will note that new claim 36 is essentially the same as claim 31 except that new claim 36 depends from claim 18. Both claims 16 and 18 have also been amended to recite elements not present in either Tasa et al. or Barnes et al. Therefore, since all elements of the recited claims are not present in the literature cited, these references cannot render claim 31 (and new claim 36) *prima facie* obvious.

Furthermore, as stated above, Tasa et al. report that heparin has an inhibitory effect on DNA synthesis reactions. Thus, Tasa et al. do not teach the use of heparin for the purpose of enhancing DNA synthesis reactions. One of ordinary skill in the art would not be motivated, after reading Tasa et al. to combine Tasa et al. with Barnes et al. to arrive at a DNA synthesis reaction with an enhancer selected from a group including heparin. As mentioned above, a reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. *Dow Chem. Co.* at 617. Therefore, Barnes et al. and Tasa et al. cannot render claim 18 *prima facie* obvious under 35 U.S.C. § 103(a).

Dependent claims 32 and 34 are non-obvious, *inter alia*, as depending from non-obvious base claims, amended claims 16 and 18.

Reconsideration and withdrawal of the obviousness rejection of claims 31, 32 and 34 are requested.


CONCLUSION

In view of the foregoing amendments and remarks, applicants believe the claims define patentable subject matter and a notice of allowance is requested. If any questions remain after consideration of the foregoing, the Office is invited to contact the applicants' attorney at the address or telephone number given herein.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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